K000882

JUN - 5 2000

Premarket Notification 510(k) Summary
As required by section 807.92
DATEX-OHMEDA CS/3 Telemetry System

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc.
3 Highwood Drive
Tewksbury, MA 01876
Tel: 978-640-0460
Fax: 978-640-0469

NAME OF CONTACT:

Mr. Joel Kent
FDA Official Correspondent

DATE:

March 16, 2000

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

DATEX-OHMEDA CS/3 Telemetry System

COMMON NAME:

Telemetry Central Monitoring System

CLASSIFICATION NAME:

The following Class III classifications appear applicable:
Arrhythmia detector and alarm (per 21 CFR 870.1025)
Monitor, ST segment with Alarm (per 21 CFR 870.1025)

The following Class II classifications appear applicable:
Cardiac Monitor (including cardiotachometer and rate alarm) (per 21CFR 870.2300)
Electrocardiograph (per 21CFR 870.2340)
Radiofrequency physiological signal transmitter and receiver (per 21CFR 870.2910)

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda CS/3 Telemetry System is substantially equivalent to two legally marketed predicate systems. The predicate device for the telemetry part is the Mortara Instrument X-12 Wireless Patient Cable (K974149) and the predicate for the central monitoring part is the HP M3150A Viridia Information Center (K993171).

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Three Highwood Drive
Tewksbury, MA 01876
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DEVICE DESCRIPTION as required by 807.92(a)(4)

The CS/3 Telemetry System consists of three main components: the ECG telemetry transmitters, the receivers combined with an antenna network and the central station software application running on a personal computer.

The transmitter is attached to the patient and acquires a continuous 12-lead ECG signal or with optional 5-wire patient cable 7 ECG leads are acquired. The signal is A/D converted and the digital data is sent to the central station using wireless radiofrequency communication. The transmitter has also a LCD display to indicate faulty electrodes and a Patient Call button, which can trigger an alarm and an ECG printout at the central station.

The antenna network receives the data sent by the transmitters. The network delivers the signal to the receivers installed in the central station PC. The receivers decode the data containing the ECG waveforms and status from the transmitters. The central station may have up to 16 receivers installed.

The central station software application retrieves the data from the receivers and performs arrhythmia and ST analysis on the signal. The results of the analysis can trigger an audiovisual alarm. The priority of each arrhythmia and ST alarm is defined in the alarm profile. The priority is divided into three different color-coded categories: red, yellow and white. The asystole and ventricular fibrillation arrhythmia alarms always have the highest (red) alarm priority and they, along with ventricular tachycardia, cannot be turned off.

The central station also displays the real-time ECG waveforms, stores waveforms, measurement data and alarms for 72 hours. The waveforms and stored data can be reviewed and printed.

Simultaneously the central station can retrieve, display and analyze ECG signals for up to 16 patients.

INTENDED USE as required by 807.92(a)(5)

The Datex-Ohmeda CS/3 Telemetry System is intended for centralized monitoring of hospital patients connected to the Datex-Ohmeda telemetry transmitter.

The Datex-Ohmeda CS/3 Telemetry System is indicated for centralized telemetric ECG monitoring of hospital patients. The monitoring includes arrhythmia and ST analysis with alarms, displaying, storing and printing the measured and calculated data.

The Datex-Ohmeda CS/3 Telemetry System is intended to be used by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda CS/3 Telemetry System is substantially equivalent to two legally marketed predicate systems. The predicate device for the telemetry part is the Mortara Instrument X-12 Wireless Patient Cable (K974149) and the predicate for the central monitoring part is the HP M3150A Viridia Information Center (K993171).

The Datex-Ohmeda CS/3 Telemetry System is a PC based solution for monitoring ECG patients connected to a Datex-Ohmeda telemetry transmitter. The system can be divided into two parts: telemetry and central monitoring. The telemetry portion is comprised of a 12-lead ECG telemetry transmitter an antenna network and the receiver board(s) installed in a commercial PC. The central monitoring portion consists of the central station software running on a commercial PC with optional connections to a local or network printer

The predicate Mortara Instrument X-12 Wireless Patient Cable (K974149) consists of the digital transmitter (Ambulatory X-12 Telemetry Module), an antenna network (Mortara Antenna Network Box(s)) and a receiver (Mortara receiver Module). ECG data is gathered and transmitted on a low power FM modulated carrier by the transmitter. The receiver demodulates and decodes the data, which is available for applications like electrocardiographs, stress test systems or monitoring systems.

The other predicate device, HP M3150A Viridia Information Center (K993171), consists of the software application running on a commercial PC retrieving patient data from the telemetry system(s) and bedside monitors. It displays and analyzes patient data, alarms and stores data for multiple patients.

Telemetry components (the transmitter, the antenna network and the receiver) of the Datex-Ohmeda CS/3 Telemetry System are essentially the same as the predicate Mortara X-12 Wireless Patient Cable. Differences are the labeling of the transmitter and the receiver board of the Datex-Ohmeda CS/3 Telemetry System includes eight receivers and the predicate Mortara receiver Module has only one receiver, but the design of receivers is the same.

The central monitoring part of the Datex-Ohmeda CS/3 Telemetry System and the predicate HP Viridia Information Center (K993171) run on a commercial personal computer using the same Windows NT operating system. Both systems have can perform arrhythmia and ST analysis and to alarm. Both systems store real-time ECG signals, parameter trends and alarms for later review. The Datex-Ohmeda CS/3 Telemetry System and the predicate HP Viridia Information Center differ in that the predicate has a network component. The Datex-Ohmeda CS/3 Telemetry System has slightly different arrhythmia detection than the predicate, but both systems give an alarm on the same arrhythmic ECG signals. The Datex-Ohmeda CS/3 Telemetry System, when compared to the HP Viridia Information Center predicate, has a different number of leads of ST analysis and ST alarms as well as the length of the stored data.

Therefore, the Datex-Ohmeda CS/3 Telemetry System is substantially equivalent to a combination of the predicate Mortara Instrument X-12 Wireless Patient Cable (K974149) and the predicate HP Viridia Information Center (K993171).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The DATEX-OHMEDA CS/3 Telemetry System is in compliance with safety standards and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance to the following mandatory and voluntary standards have been made:

- FDA regulation 21 CFR Part.898.12
- CAN/CSA C22.2 No. 601.1
- UL 2601-1
- IEC 601-2-25
- AAMI EC11-1991
- AAMI EC13-1992
- AAMI EC57:1998
- IEC 601-1
- IEC 601-2-25
- FCC Rule Part 15
- EN 60950
- IEC 601-1-2
- EN 55022
- EN 50082-1:1992

Conclusion:
The summary above shows that there are no new questions of safety and effectiveness for the DATEX-OHMEDA CS/3 Telemetry System as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2000

Datex-Ohmeda, Inc.
C/O Joel C. Kent
Manager, Quality and Regulatory Affairs
3 Highwood Drive
Tewksbury, MA 01876

Re: K000882
Trade Name: Datex-Ohmeda CS/3 Telemetry System (Release 1.00)
Regulatory Class: III (three)
Product Code: MHX
Dated: March 16, 2000
Received: March 20, 2000

Dear Mr. Kent:

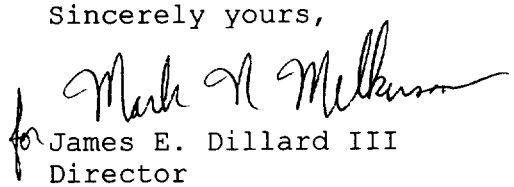
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulation.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000882

Device Name: Datex-Ohmeda CS/3 Telemetry System

The Datex-Ohmeda CS/3 Telemetry System is indicated for centralized telemetric ECG monitoring of hospital patients. The monitoring includes arrhythmia and ST analysis with alarms, displaying, storing and printing the measured and calculated data.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhern
(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K 000882